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FROM : **Galina M. Yakovleva, Ph.D.**

DEPARTMENT NAME: **Legal Division**

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DATE : **July 13, 2006**

PC17523A; Appln. No.: 10/070,530

MESSAGE:

Submitted herewith is the following:

Per your request, attached is a copy of the "Remarks" section from the May 15, 2006 Response for U.S. Patent Appln. No. 10/070,530.

Please contact me if you need any further information regarding this case.

Certificate of Mailing (37 C.F.R. § 1.8)

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office on this 13th day of July, 2006.


Christina M. Competube

Attorney Docket No. PC 17523A

REMARKS**Status of Claims**

Claims 1, 2, 4, 5, 8 and 9 are amended.

Claims 3, 6, 7, 10, and 12-22 are withdrawn as being drawn to a non-elected subject matter.

Claims 1, 2, 4, 5, 8, 9 and 11 are now pending for the Examiner's consideration.

Amendments to the Claims:

Claims 1, 2, 4, and 5 have been amended by deleting "esters, amides, and prodrugs."

Claims 1, 2, 4, 5, and 9 have been amended by deleting the non-elected subject matter.

Claim 1 has been further amended by deleting the proviso in the last two lines of Claim 1.

No new matter is added by the way of these amendments. Amendments of Claims 1, 2, 4, 5, and 9 does not constitute any admission regarding the deleted subject matter. Applicants reserve a right to pursue the deleted subject matter in this or other application(s).

Applicants respectfully request reconsideration and withdrawal of the outstanding objections and rejections, in light of the foregoing amendments and following remarks.

Claims Objection

Objection was made to Claims 1, 2, 4, 8, 9 and 11 for the reasons set forth on page 3 of the Office Action.

Claims 1, 2, 4, 5, and 9 have been amended by deleting the non-elected subject matter.

Accordingly, Applicants respectfully request that the objection be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph**Written Description**

Claims 1, 2, 4, 5, and 11 were rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth on page 4 of the Office Action.

Claim 1 has been amended by deleting the proviso in the last two lines of Claim 1 that "R^B is other than hydrogen when R^B is hydrogen and R^B is other than hydrogen when Z is C₁-C₂ alkyl."

By the present amendments, Applicants believe the rejection has been overcome, and respectfully request that the rejection be withdrawn.

Enablement

Claims 1, 2, 4, 5, and 11 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement for making any prodrug, esters generally, or amides generally. Applicants respectfully disagree with this allegation for the following reasons.

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generally, or amides generally. Applicants respectfully disagree with this allegation for the following reasons.

The originally-filed application teaches, for example, at page 15, lines 11-18 and page 16, lines 1-22 that:

"The term "pharmaceutically acceptable salts, *esters*, *amides*, and *prodrugs*" as used herein refers to those carboxylate salts, amino acid addition salts, esters, amides, and prodrugs of the compounds of the present invention which are, within the scope of sound medical judgment, suitable for use in contact with the tissues of patients without undue toxicity, irritation, allergic response, and the like, commensurate with a reasonable benefit/risk ratio, and effective for their intended use, as well as the zwitterionic forms, where possible, of the compounds of the invention."

"Examples of pharmaceutically acceptable, non-toxic *esters* of the compounds of this invention include C₁-C₆ alkyl esters, wherein the alkyl group is a straight or branched, substituted or unsubstituted, C₅-C₇ cycloalkyl esters, as well as arylalkyl esters such as benzyl and triphenylmethyl. C₁-C₄ alkyl esters are preferred, such as methyl, ethyl, 2,2,2-trichloroethyl, and tert-butyl. Esters of the compounds of the present invention may be prepared according to conventional methods.

Examples of pharmaceutically acceptable, non-toxic *amides* of the compounds of this invention include amides derived from ammonia, primary C₁-C₆ alkyl amines and secondary C₁-C₆ dialkyl amines, wherein the alkyl groups are straight or branched. In the case of secondary amines, the amine may also be in the form of a 5- or 6-membered heterocycle containing one nitrogen atom. Amides derived from ammonia, C₁-C₃ alkyl primary amines and C₁-C₂ dialkyl secondary amines are preferred. Amides of the compounds of the invention may be prepared according to conventional methods.

The term "*prodrug*" refers to compounds that are rapidly transformed *in vivo* to yield the parent compound of the above formulae, for example, by hydrolysis in blood. A thorough discussion of prodrugs is provided in T. Higuchi and V. Stella, "Pro-drugs as Novel Delivery Systems," Vol. 14 of the A.C.S. Symposium Series, and in Bioreversible Carriers in Drug Design, ed. Edward B. Roche, American Pharmaceutical Association and Pergamon Press, 1987, both of which are hereby incorporated by reference." *Emphasis added.*

Accordingly, the originally-filed specification provides sufficient enablement for making prodrugs, esters generally, or amides generally. However, solely in order to expedite prosecution of the present application, Applicants have amended 1, 2, 4, 5, and 11 by deleting the terms esters, amides and prodrugs.

Accordingly, Applicants respectfully request that the rejection be withdrawn.

Allowable Subject Matter

Applicants acknowledge with appreciation that Claims 8 and 9 would be allowable if the objection is overcome. By the present amendments, Applicants believe the objection has been overcome and respectfully request allowance of Claims 8 and 9.

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Conclusion

Applicant believes all claims are now in condition for allowance. Should there be any issues that have not been addressed to the Examiner's satisfaction, Applicant invites the Examiner to contact the undersigned attorney.

Applicant does not believe any fees are due in connection with this response. If any fees are due in connection with this response, please charge such fees to Deposit Account No. 500329.

Respectfully submitted,

Date: May 15, 2006

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